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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,862	09/08/2000	Keith Henry Stockman Campbell	112800.301	2555

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EXAMINER
CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
1632	16

DATE MAILED: 05/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/658,862	STOCKMAN CAMPBELL ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/803,165* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's arguments filed February 28, 2003 in paper no. 14 have been fully considered but they are not persuasive. The amendment has been entered. Pending claims are 57-71. The declaration by David Wells has been considered but not deemed persuasive.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 57-68 and 71 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 92-127 and 130 of copending Application No. 09/225,233. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The claims are to a product, nonhuman embryo clones and nonhuman mammalian clones, produce by process. While the process steps themselves are obvious over each other, the products are identical.

Applicant argues that the inventions presently claimed and those in '233 are not the "same" invention as defined under 101 because the present claims could be infringed without infringing those in '862. This argument is not persuasive.

The products, while made by materially different and separate methods, are the same. There is no patentable distinction between them. The methods of making do not affect the product being claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438,
164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the

conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 57-68 and 71 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11-18 of U.S. Patent No. 6,252,133 B1. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed cloned nonhuman embryos, cloned nonhuman mammals and reconstituted nonhuman mammalian oocyte are made a process claimed in '133.

The present claims are drawn nonhuman embryo clones, nonhuman mammal clones and reconstructed oocytes that contain the same set of chromosomes as a pre-existing, nonhuman, non-embryonic mammal by nuclear transfer of a nucleus from a G1 donor cell. The embryo clone is produced by nuclear transfer of a diploid donor cell in the G1 phase of the cell cycle into an MII oocyte of the same species as the cell, followed activation and culture. To produce the mammal, the embryo clone is transferred to a recipient female of the same species as the cell. The donor cell is from a pre-existing, nonhuman, non-embryonic mammal. The reconstructed nonhuman mammalian oocyte comprises a nucleus of a differentiated nonhuman mammalian diploid donor cell from the same species in the G1 phase of the cell cycle and is capable of developing to term. Claims 11-18 of '133 are to methods of reconstructing an embryo of a nonhuman mammal comprising a donor diploid cell in the G1 phase of the cell cycle into an unactivated, enucleated MII phase oocyte of the same species as the cell, maintaining the reconstructed embryo without activation in the presence of a microtubule stabilizer or inhibitor, activating the reconstructed embryo, and, transfer the reconstructed embryo to a female of the same

species, to produce the mammal. The donor cells of the present claims fall within the scope of "diploid donor cell" of the claims in '133, and donor cells are defined in the specification as coming from a pre-existing, nonhuman mammal non-embryonic mammal. An incubation step with microtubule stabilizers or inhibitors is defined in the present specification, activation is defined in the present specification as taking place with or without the stabilizers or inhibitors, and activation is defined as being by fusion. '133 claims a mammal is produced by transferring the embryo to a female mammal of the same species.

Therefore, at the time of the instant invention, it would have been obvious to the ordinary artisan to produce a cloned nonhuman embryo or a cloned nonhuman mammal as presently claimed given the method steps of claims 11-18 in '133.

Applicant agreed to file a terminal disclaimer to U.S. Patent No. 6,252,133 B1 once allowable subject matter is identified.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57-64, 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 57, 61, 69 and 70 each contain the phrase "same set of chromosomes." However, the specification does not provide support for this phrase. Applicant should specifically point out where in the specification support for this phrase can be found. There is no discussion in the specification that the clones contain a "same set of chromosomes. Further, this phrase does not occur in the originally filed claims. Without support, there is no evidence that applicant contemplated that the clones would contain "same set of chromosomes" at the time of filing.

In addition, claim 69 is drawn to nonhuman, non-embryonic mammal from which a differentiated cell has been taken and a clone thereof, wherein the clone has the same set of chromosomes as the nonhuman mammal. Claim 70 is drawn to a cell culture comprising nonhuman mammalian differentiated cells and a clone thereof, wherein the cloned has the same set of chromosomes as the cells in the culture. The specification does not contemplate either a nonhuman, mammal and a clone of the mammal nor nonhuman mammalian differentiated cells and clone produced from the cells as a product, kit or any other invention. Applicant needs to provide specific support for the contemplation of the two products as one invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 92, 95, 101, 108, 109, 116, 119, 121, 123, and 126-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 57, 61, 69 and 70 have the phrase "has the same set of chromosomes as a pre-existing mammal." However, there is no definition of "same set" in the specification. Does applicant mean the same chromosomes that were in the parent, chromosomes that have identical nucleotide sequence, chromosomes that have the same karyotype or a group of chromosomes having the same number as the pre-existing mammal? Applicant is requested to point out the definition for this phrase by page and line number.

Claims 57, 65 and 71 state "is capable of developing to term" which is confusing as to the metes and bounds of the claim. Is an embryo that doesn't develop to term included in the claim? If only embryos that develop to term are included, won't the embryo be gone by the time the subject matter is realized? If the embryo isn't permitted development to term, is it included in the subject matter of the claim?

Claims 65 and 67 are unclear as if the donor cell is genetically modified, then the resulting mammalian embryo or mammal cannot be a clone.

Claims 69 and 70 are unclear as to the scope of "nonhuman mammalian clone." Does application intend the scope to a cloned nonhuman mammal or cloned cells?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57-64 and 71 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent 5,057,420 issued October 15, 1991 (Massey) for reason set forth in the office action mailed December 19, 2001 in paper no. 6.

Massey teaches bovine embryos isolated from cows that have been artificially inseminated (col. 3, lines 18-31). Bovine embryos encompassed by the present claims and made by a particular process of the claims do not have a property that distinguishes them from those bovine embryos taught by Massey. That the claimed embryos have the same set of chromosomes as a nonhuman, non-embryonic mammal does not provide a distinguishing feature to the resultant embryo, as the source of the embryo's chromosomes does not affect the embryo.

Claims 57-64 and 71 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by The Science of Providing Milk for Man, Campbell and Marshall, McGraw Hill Book Co., New York, 1975, pages 48, 49, and 51-56 for the reasons presented in the office action mailed December 19, 2001 in paper no. 6.

At pages 48,49 and 51-56, Campbell and Marshall teach several different bovines that existed prior to applicant's invention. A bovine produced by the claimed methods would not be patentably distinct from any one of the bovines of Campbell and Marshall as the

method of producing does not provide a patentably distinguishing feature to the claimed mammal. That the claimed mammals have the same set of chromosomes as a nonhuman, non-embryonic mammal does not provide a distinguishing feature to the resultant mammal, as the source of the mammal's chromosomes does not affect the mammal.

Applicant's mammals are clones of embryos and mammals that existed prior to the claimed invention. The claims state that.

Claims 57-64 and 71 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147 for the reasons presented in the office action mailed December 19, 2001.

Sims teaches the production of bovines and bovine embryos by nuclear transfer, where the donor nucleus is from a bovine cultured inner cell mass cell (page 6145, col. 2, parag. 2, lines 1-7 and page 6146, col. 1, parag. 2, lines 6-11). The source of the donor nucleus, be it bovine inner cell mass cell or a non-embryonic cell as claimed, does not provide a patentable distinction on the resulting bovine embryo or bovine. The source of the donor nucleus does not alter the bovine embryo or bovine such that the bovine embryo or bovine encompassed by applicant's claims is patentable distinct from those of Sims et al. Indeed, the bovine embryo and bovine of Sims contains the same set of chromosomes as a non-embryonic bovine of the same species, that is the same chromosomes as the donor bovine.

Claims 65-68 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 95/17500 published 29 June 1995 (Stice).

Stice teaches transgenic nonhuman mammalian embryos and transgenic nonhuman mammals produced by nuclear transfer where the nuclear donor is an embryonic cell comprising a genetic modification (page 33, lines 14-24). The source of the donor nucleus, be it a genetically modified nonhuman embryonic cell as Stice teaches or a genetically modified non-embryonic, nonhuman mammalian cell as claimed, does not provide a patentable distinction on the resulting genetically modified nonhuman embryo or genetically modified nonhuman mammal. The

source of the donor nucleus does not alter the embryo or mammal such that the embryo or mammal encompassed by applicant's claims is patentable distinct from those of Stice et al. Further, Stice teaches that the cells are cultured *in vitro* and are abstracted *ex vivo* (page 6144, 1, 8-15).

Applicant argues that each cited reference teaches the conventional process of producing embryos by fertilization of an egg by a sperm. Applicant argues that conventional reproduction and cloning using a conventional embryo as the source of donor cells do not permit the selection of an existing mammal that has advantageous characteristics and make a genetic copy of it. Applicant argues that the mixing of genetic material from separate parents results in an offspring with an unpredictable mixture of genetic traits. Applicant argues that the use of a differentiated cell from the mammal to be cloned, a pre-existing mammal, prevents any unpredictability resulting from the mixing of parental genomes. Applicant argues that there is need for only one parent to produce the claimed mammals, and not two as in the references. Declarant Wells supports applicant's arguments in stating that the references do not teach the production of mammals from "one parent" or mammals that contain the same set of chromosomes as a prior existing embryo or mammal. These arguments are not persuasive.

Regardless of how the mammals were actually produced in the prior art, there are no identifying characteristics or features of the claimed mammals that would distinguish them from the mammals in the art. For example, the Merino sheep taught by McLaughlin cannot be distinguished from Merino sheep of applicant's claims. In a side-by-side comparison of McLaughlin's sheep and sheep of applicant's claims, there would be no patentably distinguishing differences. Another way to look at the issue, is if there were two Merino sheep in the yard, how could one tell which was produced by sexual reproduction and which was produced by cloning; which had a genome from two parents, versus one that had one a genome of one parent. Once the embryo or mammal is made, how it was made cannot be discerned. In fact, one of the sheep would be prior existing. Again, the examiner does not see any patentably distinguishing characteristics or features of the sheep presently claimed and those of McLaughlin. This same argument applies to the claims to pig, goat, mouse, rabbit and cow as claimed. The limitation provided by "same set of chromosomes as the pre-existing mammal" does not distinguish from the art. In fact it admits that

the mammals of the claims are the same as the nuclear donor mammals, and thus known in the art at the time of filing. Thus, a clone of any one of the mammals in the cited prior art would be the same as a mammal of the claims. They both would have the "same set of chromosomes."

With regard to "same set of chromosomes," without a clear definition of what is meant by this phrase, and mammal of the same species would have the same number of chromosomes, the same genes on the chromosomes and the same chromosome structure, such as by RFLP analysis, as examples. In this regard, if same set means same number of chromosomes, then the mammals in the cited prior art would certainly anticipate the claims. Further, if same set means same karyotype, same RFLP analysis or same genomic sequence, applicant needs to supply such information as the patent office does not have facilities to test the art products and the claimed products. See *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977).

Applicant argues that patentably should turn on novelty and nonobviousness, and not how the mammal looks and behaves. Applicant argues that the limitation that the cloned embryo and mammal has the same set of chromosomes of a pre-existing, non-embryonic mammal from which a differentiated cell has been taken is the distinguishing feature. Applicant questions the statutory authority for a side-by-side comparison of products. Applicant states that very few patentable articles are immediately recognizable as being patented unless they are marked. These arguments are not persuasive.

The lack of novelty is the basis for the art rejections of record. The claimed cloned embryos and mammals are not novel because they are copies of embryos and mammals that existed before. References to looks and behavior in the previous office action were meant to establish that there are no features of the claimed embryos and mammals due to the genome content. These cloned embryos and mammals are indistinguishable from those embryos and mammals in the prior art, and that they neither look nor behave any differently than those mammals. The source of genome or the number of parents do not affect the resultant mammals such that patentable differences arise. The fact is no difference could be told between a three- year old "nuclear donor" mammal and its clone as an example. This is the basis of the rejection. The clone and the nuclear donor mammal are indistinguishable, or if they aren't

applicant has not argued or stated such distinction. A side-by-side comparison doesn't require statutory authority. It is merely one method through which the prior art mammals and those of the claims can be distinguished. Further, the side-by-side comparison was not intended to be only for physical differences. A side-by-side comparison provides no differences between the mammals of the cited art and those of the claims in any area of comparison. The genomes are the same, and, thus, the mammals are duplicates of one another. How can the mammal in the art differ from that of the claim when they are genetically identical? To be complete, none of the examiner's arguments were directed to the need to mark a product for infringement purposes. That is beyond the scope of an examiner's function, as stated by applicant.

Applicant states that they do not contest that a cloned cow or a cloned cow embryo covered by the present claims will generally look like any other cow or cow embryo clone, including those taught in the references and the parent animals from which the clone derives. Applicant argues that the examiner is ignoring their limitations and that these limitations are absent in the cited art. Applicant argues that the mammals and mammalian embryos cited are not clones of a pre-existing, non-embryonic mammal from which differentiated cells have been taken. Applicant argues that this is a structural limitation that distinguishes the claimed embryos and mammals from those in the cited prior art.

The limitation "has the same set of chromosomes as a prior existing mammal" is not a structural limitation to the cloned embryo or product. This does not provide any type of feature that can distinguish the prior mammal from the cloned product. A clone of the mammals of the art, or their embryos, cannot be distinguished structurally from the donor prior-existing mammal. The donor and their clones would be identical genetically. A clone of any mammal in the cited prior art would be the same as the mammal of the art. There would be no patentably distinct feature.

Applicant argues that it is not possible for a clone and the nuclear donor not to be distinguished. Applicant argues that the phenotype of any mammal is determined by genetic and environmental factors. Applicant argues that since the mammals of the claims would have different genomic compositions and be raised in different environments, the mammals and the clones will have distinguishing characteristics.

Applicant argues that the differences in chromosomal content could be easily determined. Applicant argues that the clones and the parent animal would be of different ages. This argument is supported by the Dr. Wells, declarant.

The claims do not contain any limitations to phenotypic characteristics of the cloned mammals over those of the art. Any such features applicant should include in the claim so that these features can be examined. While genetic differences can be distinguished by known methods, the methods supplied by Dr. Wells would not find differences between the mammals and embryos of the cited prior art and their clones. Also, it is not seen how differences between mammals that do not alter their function, use, biology, biochemistry or any other aspect of their existence would provide a patentable different. It is not seen, as an example, how a cow with a crooked horn would be patentable distinct over a cow with a straight horn. Alterations due the environment do not necessarily imbue patentable distinction.

Furthermore, the claims state "pre-existing mammal." This includes mammal embryos. As the cited prior art produced clones from prior existing mammal embryos, the cited art clearly anticipates the "pre-existing mammal."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Reynolds, SPE of AU 1632 whose telephone number 703-305-4051. The examiner can normally be reached on M-Th.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

D.C.
May 8, 2003